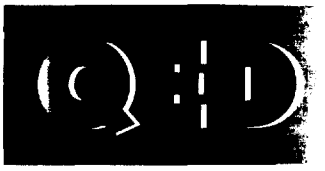

December 8, 1998

Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs (HFZ215)
1350 Piccard Avenue
Rockville Center, MD 20850

To Whom It May Concern:

"513(e) Petition"

The accompanying documents support our Petition for Reclassification of Fiber Optic Light Sources.

If the documents require clarification or if additional information is required please contact me at 606-231-0338 or FAX 606 231-0376.

Ira Cooper
President/CEO

99P-0895

CCP1

QED, Inc.
750 Enterprise Drive, Lexington, Kentucky USA 40510
(800) 513-2256 • (606) 231-0338 • Fax (606) 231-0376

PETITION FOR RECLASSIFICATION OF A MEDICAL DEVICE

It is requested that the Classification of Fiber Optic Light Sources, 78 FCW-Regulation 876-1500 be changed from Class ll to Class l.

The referenced Light Sources are not implantable devices; are non-invasive; do not come in contact with the patient's body; are not life sustaining or life supporting.

The light sources do not require special controls, and are approved under UL Safety Standards for Medical Devices, UL 2601.
There is no potential hazard to the patient or the medical personnel.
There is sufficient information to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness.

> EUROPEAN UNION MEDICAL DEVICES DIRECTIVE 93/42 EEC
> ANNEX IV CLASSIFICATION III NON-INVASIVE DEVICES 1.1
> Rule 1. States:
> **"All non-invasive devices are Class l unless one of the rules set out hereinafter applies:**
> **Non-invasive devices intended for channeling or storing blood, body liquids or tissue, liquids or gasses for the eventual infusion, administration or introduction into the body which would be Class ll."**
>
> **The CDRH checklist "General Device Classification" questionnaire states that if the device is:**
> - **Not life supporting**
> - **Not a device for a use which is of substantial importance in preventing impairment of human health.**
> - **Does not present a potential unreasonable risk of illness or injury.**
> - **There is sufficient information to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness, then the Device is Class l."**

The 876.1500 light sources conform to both of the above criteria.

While it is understood that FDA (CDRH) would not lower its standards if it was necessary to meet the European Directives, it is

felt that both the EU MDD and the CDRH checklist describe the 876.1500 light sources.

We do not recommend exemptions to Registration, Records and Reports or cGMP/ Quality Systems.

W.D REED
Director,
Regulatory Affairs
QED Inc.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE — FOOD AND DRUG ADMINISTRATION

GENERAL DEVICE CLASSIFICATION QUESTIONNAIRE

FORM APPROVED: OMB NO. 0910-0138
EXPIRATION DATE: January 1, 2000
(See OMB Statement on Page 2)

PANEL MEMBER / PETITIONER: QED INC, 150 ENTERPRISE DR LEXINGTON 40510

DATE: 12/5/98

GENERIC TYPE OF DEVICE: FIBER OPTIC LIGHT SOURCES

CLASSIFICATION RECOMMENDATION: CLASS I

1. IS THE DEVICE LIFE-SUSTAINING OR LIFE-SUPPORTING ?	☐ YES ☒ NO	Go to Item 2.
2. IS THE DEVICE FOR A USE WHICH IS OF SUBSTANTIAL IMPORTANCE IN PREVENTING IMPAIRMENT OF HUMAN HEALTH ?	☐ YES ☒ NO	Go to Item 3.
3. DOES THE DEVICE PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY ?	☐ YES ☒ NO	Go to Item 4.
4. DID YOU ANSWER "YES" TO ANY OF THE ABOVE 3 QUESTIONS ?	☐ YES ☒ NO	If "Yes," go to Item 7. If "No," go to Item 5.
5. IS THERE SUFFICIENT INFORMATION TO DETERMINE THAT GENERAL CONTROLS ARE SUFFICIENT TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☒ YES ☐ NO	If "Yes," Classify in Class I. If "No," go to Item 6.
6. IS THERE SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☐ YES ☒ NO	If "Yes," go to Item 7. If "No," Classify in Class I.
7. IS THERE SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ? IF YES, CHECK THE SPECIAL CONTROL(S) NEEDED TO PROVIDE SUCH REASONABLE ASSURANCE. FOR CLASS II. ☐ Postmarket Surveillance ☐ Performance Standard(s) ☐ Patient Registries ☐ Device Tracking ☐ Testing Guidelines ☐ Other (specify)	☐ YES ☐ NO	If "Yes," Classify in Class II If "No," Classify in Class III
8. IF A REGULATORY PERFORMANCE STANDARD IS NEEDED TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS OF A CLASS II OR III DEVICE, IDENTIFY THE PRIORITY FOR ESTABLISHING SUCH A STANDARD. ☐ Low Priority ☐ Medium Priority ☐ High Priority N/A ☐ Not Applicable		
9. FOR A DEVICE RECOMMENDED FOR RECLASSIFICATION INTO CLASS II, SHOULD THE RECOMMENDED REGULATORY PERFORMANCE STANDARD BE IN PLACE BEFORE THE RECLASSIFICATION TAKES EFFECT ?	☐ YES ☐ NO ☒ NOT Applicable	
10. FOR A DEVICE RECOMMENDED FOR CLASSIFICATION / RECLASSIFICATION INTO CLASS III, IDENTIFY THE PRIORITY FOR REQUIRING PREMARKET APPROVAL APPLICATION (PMA) SUBMISSIONS. ☐ Low Priority ☐ Medium Priority ☐ High Priority N/A ☐ Not Applicable		

11a. CAN THERE OTHERWISE BE REASONABLE ASSURANCE OF ITS SAFETY AND EFFECTIVENESS WITHOUT RESTRICTIONS ON ITS SALE, DISTRIBUTION OR USE, BECAUSE OF ANY POTENTIALITY FOR HARMFUL EFFECT OR THE COLLATERAL MEASURES NECESSARY FOR THE DEVICE'S USE ?	☒ YES ☐ NO	If "Yes," go to Item 12. If "No,", go to Item 11b.
11b. IDENTIFY THE NEEDED RESTRICTION(S) *(If Item 11a. was checked "NO.")* ☐ Only upon the written or oral authorization of a practitioner licensed by law to administer or use the device ☐ Use only by persons with specific training or experience in its use ☐ Use only in certain facilities ☐ Other (Specify) _____	N/A	

12. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs (HFZ-215)
1350 Piccard Drive
Rockville, MD 20850

OMB STATEMENT

Public reporting burden for this collection of information is estimated to average 1-2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS Reports Clearance Officer, Paperwork Reduction Project (0910-0138)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

(Please DO NOT RETURN this form to this address.)

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Supplementary Data Sheet
Summary of Reasons for Classification

1. Device Name FIBER OPTIC LIGHT SOURCE

2. Classification Panel 78 FCW REGULATION 876 - 1500

3. Is device an implant? NO

4. Indications for use prescribed, recommended, or suggested in the device's labeling that were considered by the panel NO

5. Identification of any risks to health presented by device

General NONE

Specific Hazards to Health		Characteristic or Feature of Device Associated with Hazard	
a.	/	a.	
b.	None	b.	N/A
c.	None	c.	
d.	/	d.	

6. Recommended panel classification and priority

Classification	Priority (Class II or III Only)
CLASS I	

7. If device is an implant, or is life-sustaining or life-supporting, and has been classified in a category other than Class III, explain fully reasons for the lower classification with supporting documentation and data

N/A

8. Summary of data including clinical experience or judgment upon which classification recommendation is based

None invasive
No hazard to patient or med personnel
Safety (UL) Tested & approved

9. Identification of any needed restrictions on the use of the device

None

10. If device is in Class I, recommend whether FDA should exempt it from:

	Justification/COMMENTS
a. Registration	a. NO CHANGE
b. Records and Reports	b. RECOMMENDED
c. Good Manufacturing Practice	c.

11. Existing standards applicable to the device, device subassemblies (components), or device materials (parts and accessories)

c GMP/QUALITY SYSTEMS

CLASSIFICATION QUESTIONNAIRE FORM

Medical Device Classification System

Panel Member: _____ Date: 12/5/98

Device: FIBER OPTIC LIGHT SOURCE

Use Categories: ☐ Diagnostic ☐ Monitoring ☐ Prosthetic ☐ Surgical ☐ Therapeutic ☐ Other

Regulatory Level: (I. General Controls) II. Performance Standards III. Premarket Approval Specific device problems: Yes (No)

Classification System	Yes	No	Do Not Know	Regulatory Level	Question Scheme
1. Custom Made?		X			Yes--2 No--3
2. Custom Made: Standard?		X			Yes / No 17
3. Life-sustaining?		X			Yes--5 No--4
4. Potentially hazardous to life, good health		X			Yes / DNK } 5 No--7
5. (a) Can standards be developed now; and (b) would standard be adequate?	X				Yes--7 No / DNK--6
6. Marketed in U.S.?	X				Yes / No } 7
7. Remote from body?	X				Yes--14 No / DNK } 8
8. Powered?	X				Yes--9 No--13
9. Failure of power: hazardous to patient?		X			Yes / DNK / No } 10
10. Introduce energy into body?		X			Yes--11 No--13
11. Acceptable energy levels?		/			Yes / No } 12
12. Safe energy levels if malfunction?	/				Yes / No / DNK } 13
13. Material regarded as safe without standard:	X				Yes / No / DNK } 14
14. Prescriptions needed? limitation, hazards, difficulties, problems		X			Yes / No } 15
15. Labeling, instructions or precautions on measurement function?		X			Yes / No } 16
16. Performance Standards?					Yes / No } 17
17. Special safety systems considerations?		X			Yes / No / DNK } 18
18. Potentially hazardous to fetus and/or gonads		X			Yes / DNK } To Ob-Gyn Panel
Low Density Coding Form		X			

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE — FOOD AND DRUG ADMINISTRATION

SUPPLEMENTAL DATA SHEET

FORM APPROVED: OMB NO. 0910-0138
EXPIRATION DATE: January 1, 2000
(See OMB Statement on Page 2)

1. GENERIC TYPE OF DEVICE: FIBER OPTIC LIGHT SOURCES (78 FCW, Reg: 876.1500

2. ADVISORY PANEL

3. IS DEVICE AN IMPLANT ?
☐ Yes ☒ No

4. INDICATIONS FOR USE PRESCRIBED, RECOMMENDED, OR SUGGESTED IN THE DEVICE'S LABELING THAT WERE CONSIDERED BY THE ADVISORY
SAFETY UL 2601

5. IDENTIFICATION OF ANY RISKS TO HEALTH PRESENTED BY DEVICE
General NONE

Specific Hazards to Health	Characteristics or Features of Device Associated with Hazard
a.	a. N/A
b. NONE	b.
c.	c.
d.	d.

6. RECOMMENDED ADVISORY PANEL CLASSIFICATION AND PRIORITY
Classification Priority (Class II or III Only)

7. IF DEVICE IS AN IMPLANT, OR IS LIFE-SUSTAINING OR LIFE-SUPPORTING AND HAS BEEN CLASSIFIED IN A CATEGORY OTHER THAN CLASS III, EXPLAIN FULLY, THE REASONS FOR THE LOWER CLASSIFICATION WITH SUPPORTING DOCUMENTATION AND DATA
N/A

8. SUMMARY OF INFORMATION, INCLUDING CLINICAL EXPERIENCE OR JUDGMENT, UPON WHICH CLASSIFICATION RECOMMENDATION IS BASED

9. IDENTIFICATION OF ANY NEEDED RESTRICTIONS ON THE USE OF THE DEVICE
NONE

10. IF DEVICE IS IN CLASS I, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM

Justification / Comments

- ☐ a. Registration / Device Listing
- ☐ b. Premarket Notification
- ☐ c. Records and Reports
- ☐ d. Good Manufacturing Practice

NOT RECOMMENDING CHANGES

11. EXISTING STANDARDS APPLICABLE TO THE DEVICE, DEVICE SUBASSEMBLIES *(Components)* OR DEVICE MATERIALS *(Parts and Accessories)*

12. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO:

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1350 Piccard Drive
Rockville, MD 20850

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